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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,094	08/22/2000	Henry Buchwald	12335.1USWO	8850

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,094	BUCHWALD ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- Th MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-25 and 35-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,12-15,17-25,36,41,42 and 55* is/are rejected.

7)☒ Claim(s) *8,10,11,35,37-40 and 43-54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is indefinite since the preamble of the claim recites a method for determining a patient's blood oxygen transport. However, none of the steps of the method refer back to this function. Rather, the steps of the method recite determining a patient's blood lipid level. How is a patient's blood lipid level related to their blood oxygen transport?

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 55 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1 of U.S. Patent No. 6,037,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to measure a patient's blood lipid levels at different times and to compare these levels as an indication of blood oxygen transport in the patient in order to determine if the patient's blood lipid levels have lowered or increased over time, thus serving as an indication that the patient is either receiving or not receiving enough oxygen to tissues for healthy maintenance and survival.

5. Claims 1-7, 9, 12-19, 23-25 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 15-19, 24, 34-36, 39-40, 48-50 and 52-53 of copending Application No. 09/645,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for determining a patient's susceptibility to angina by obtaining a blood sample from a patient, measuring a rate of oxygen diffusion across a membrane of a red blood cell of the blood sample, and correlating the measured rate with a susceptibility to angina in a control population or in the patient at the measured rate, as well as correlating the measured rate with conditions of the patient under stress such as a cardiac stress test. The broad steps recited in claim 1 of application serial no. 09/645,236 are included within the method recited in instant claim 1. In addition, both sets of claims recite an apparatus for measuring the diffusion of oxygen across a red blood cell membrane comprising an oxygen level detector, a gas exchange system and a red blood cell transport system, wherein the red blood cell transport system comprises a pump to transport a red blood cell to the gas exchange system, the gas exchange

system comprises a gas permeable tubing in a housing for diffusing gas from the housing to a red blood cell contained in the tubing, and the oxygen level detector is one of an oxygen electrode, a spectrophotometric detector or a fluorometric detector.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 15, 17, 19, 22-23, 36 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. (from Chapter 9- Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure Statement filed December 29, 2000).

Page et al. teach of an apparatus for measuring diffusion of oxygen across a red blood cell membrane, which comprises a microflow system that serves as a red blood cell transport system, an oxygen level detector and a gas exchange system. The gas exchange system comprises a capillary imbedded in a thin film of silicone rubber. Test blood samples are held in a reservoir and withdrawn by a syringe pump that acts as the red blood cell transport system into

the capillary lumen where gas exchange occurs. In an oxygen uptake experiment, both surfaces of the capillary are exposed to humidified air and a fully deoxygenated sample is oxygenated as it flows through the lumen of the capillary. In an oxygen release experiment, both surfaces of the capillary are exposed to humidified nitrogen and a fully saturated blood sample is deoxygenated as it flows through the lumen of the capillary. A shroud surrounds the capillary and serves as a housing that holds the desired oxygen atmosphere around the capillary. The shroud has windows at the top and bottom to allow the passage of light. The oxygen level detector comprises a microspectrophotometer which makes absorbance measurements at various axial positions along the capillary. A data acquisition and control system controls the axial positioning of the apparatus and the logging of absorbance and other data.

Page et al fail to specifically teach that successive samples of red blood cells are exposed to gases in the capillary without cross-contamination between the samples. However, this limitation would have been obvious to one of ordinary skill in the art in view of the teaching of Page et al that the gas permeable tubing (i.e. capillary) is a lumen that contains red blood cells, that successive samples of red blood cells are exposed to gases as depicted and described with reference to Figure 9.6 of Page et al., and that the system is flushed with water between runs. See the first paragraph on page 138 of Page et al.

It appears that this reference to Page et al. was published in 1996 since the other Page et al. article cited in the Information Disclosure Statement dated 12-29-00 (from Microvascular Research) indicates that this Page et al. reference, in the lower right hand corner of page 55, was published in 1996.

9. Claims 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. in view of Applicants' admitted prior art. For a teaching of Page et al. (from Chapter 9-Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure Statement filed December 29, 2000), see previous paragraphs in this Office action. Page et al. fail to teach that the oxygen level detector can be a fluorometric detector.

Applicants admit on lines 1-10 of page 5 in the instant specification that oxygen levels in blood are known in the art to be measured by spectrophotometric methods, fluorometric methods and potentiometric methods utilizing oxygen electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a fluorometric detector in place of the spectrophotometric detector taught by Page et al. as the oxygen level detector since a fluorometric detector is a known prior art method of measuring oxygen levels in blood equivalent in function to a spectrophotometric detector.

It also would have been obvious to one of ordinary skill in the art to use a peristaltic pump or an aspirator in place of the syringe pump taught by Page et al. for transporting a red blood cell sample to the capillary gas exchange system in the apparatus of Page et al. since peristaltic pumps and aspirators are known in the art to perform the equivalent functions of a syringe pump for injecting and transporting fluid samples.

10. Claims 8, 10-11, 35, 37-40 and 43-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's arguments filed July 7, 2003 have been fully considered but they are not persuasive.

The previous rejections of the claims made under 35 USC 112, second paragraph in the last Office action dated January 7, 2003 have been withdrawn as necessitated by Applicants'

amendments to the claims. However, a new rejection of claim 55 under this statute is set forth above.

All previous double patenting rejections under 35 USC 101 made in the last Office action have been withdrawn in view of Applicants' amendments to the claims. In view of the cancellation of claims 28-33, the rejection of these claims under the judicially created doctrine of obviousness-type double patenting has also been withdrawn. Claim 55 is newly rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claim 1 of US Patent no. 6,037,181 for the reasons set forth above. Applicants are requested to file an appropriate terminal disclaimer over US Patent no. 6,037,181 to obviate this rejection and any future rejections based upon this patent if and when the instant claims are amended. The previous provisional rejection of some of the instant claims over pending claims in application serial no. 09/645,236 is also maintained for the reasons set forth above, and since an appropriate terminal disclaimer has not been filed to obviate this rejection. Because of the inclusion of some different claims in this rejection not previously included in the last Office action, this Office action is not being made final.

Applicants argue the rejection of the claims under 35 USC 102 and 35 USC 103 as being anticipated and obvious over Page et al by stating that Page et al does not disclose a system having a housing that exposes successive samples of red blood cells to gases without cross-contamination between the samples. In response to this argument, it is noted that the system taught by Page et al includes a gas permeable tubing (i.e. capillary) that functions as a lumen to hold and expose successive samples of red blood cells to gases. See Figure 9.6 in Page et al that describes multiple samples of red blood suspensions and red blood cell/hemoglobin mixtures

passing through the capillary. In addition, Page et al teach that the system is flushed with water between runs. See the first paragraph on page 138 of Page et al. Therefore, it would have been obvious to one of ordinary skill in the art to recognize that the system taught by Page et al is capable of exposing successive samples of red blood cells to gases without any cross-contamination between the samples since flushing of the capillary occurs between runs of different red blood cell suspensions. Because the limitation of now cancelled claim 34 (added to claim 15) was not addressed in the previous Office action, this Office action is not being made final.

For all of the above reasons, Applicants' arguments are not found persuasive.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is (703) 308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

mmw
September 8, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700